107TH CONGRESS 1ST SESSION

S. 1132

To amend the Federal Food, Drug, and Cosmetic Act relating to the distribution chain of prescription drugs.

IN THE SENATE OF THE UNITED STATES

June 28, 2001

Mr. Crapo introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act relating to the distribution chain of prescription drugs.

- 1 Be it enacted by the Senate and House of Representatives
- 2 of the United States of America in Congress assembled,

3 SECTION 1. PRESCRIPTION DRUG DISTRIBUTION.

- 4 (a) Definition of Authorized Distributor.—
- 5 (1) In General.—Section 503(e)(4) of the
- 6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 353(e)(4)) is amended by striking "(4) For the pur-
- 8 poses" and all that follows through "means distribu-
- 9 tion" in subparagraph (B) and inserting the fol-
- lowing:

1	"(4) Definitions.—In this subsection and
2	subsection (d):
3	"(A) AUTHORIZED DISTRIBUTOR.—
4	"(i) In general.—The term 'author-
5	ized distributor' means a distributor to
6	which a manufacturer sells a prescription
7	drug.
8	"(ii) Effective time period.—A
9	distributor that purchases a prescription
10	drug from a manufacturer shall be treated
11	as an authorized distributor with respect to
12	that prescription drug for a period of 12
13	months following the date of the purchase.
14	"(B) Wholesale distribution.—The
15	term 'wholesale distribution' means distribu-
16	tion.".
17	(2) Conforming amendments.—Section 503
18	of the Federal Food, Drug, and Cosmetic Act (21
19	U.S.C. 353(e)(4)(A)) is amended in subsections (d)
20	and (e)—
21	(A) by striking "authorized distributor of
22	record" each place it appears and inserting
23	"authorized distributor"; and

1	(B) by striking "authorized distributors of
2	record" each place it appears and inserting
3	"authorized distributors".
4	(b) REQUIRED STATEMENT.—Section 503(e)(1)(A)
5	of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6	353(e)(1)(A)) is amended by inserting "a statement that
7	the drug was first purchased from or through an author-
8	ized distributor or" after "who receives the drug".

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